

# 2002 FDA Edition

What's New in InfinityQS 2002

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# What's New in Infinity QS 2002

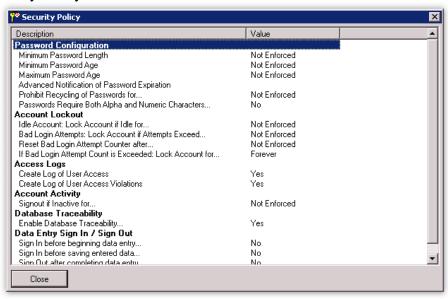
InfinityQS SPC 2002 has undergone a vital transformation that includes major improvements affecting security, functionality and usability. Security features have been enhanced to satisfy even the strictest interpretation of the *FDA 21 CFR Part 11 - Electronic Records and Electronic Signatures* requirement. Though this enhancement is vital to our users governed by the FDA, it also benefits all users wishing to ensure the integrity of their data through good security practices. Other important changes include improved user interface, additional Six Sigma features, automated WEB publishing and enhanced integration with external applications.

#### FDA 21 CFR Part 11 Enhancements

#### Security Policies in InfinityQS

The security policy implementation within InfinityQS 2002 will have a similar look-and-feel to that embedded in the Windows 2000 Local Security Policy interface found under the operating system's Administrative Tools.

Within InfinityQS 2002, security policies will be managed from the InfinityQS 2002 Database Manager application. The user-interface illustrated below provides a comprehensive report-style display of all Security Policy items.



To modify any setting, simply double-click the appropriate item. Following is a brief explanation of the new security policies that are part of the InfinityQS 2002 release.

#### **Password Configuration**

The following policies all relate to Password setup and maintenance.

#### Minimum Password Length

This policy dictates the minimum number of characters allowed for all passwords and sign in names entered into the system.

Default: Not Enforced

Default when Enforced: 8 Characters

Allowable Settings: 1 - 31 Characters



#### Minimum Password Age

InfinityQS keeps track of when the user last changed their password. This policy dictates when the user is allowed to change their password again.

Default: Not Enforced

Default when Enforced: 15 Days

Allowable Settings: 1 – 365 Days (but also limited by the Maximum

Password Age and Advanced Notification settings)



#### Maximum Password Age

Based on the last time a user changed their password, this policy dictates when the user's password WILL expire and MUST be changed.

Default: Not Enforced

Default when Enforced: 30 Days

Allowable Settings: 1 – 365 Days (but also limited by the Minimum Password Age and Advanced Notification settings)



#### Advanced Notification of Password Expiration

This setting determines the number of days prior to password expiration that the user is notified and allowed to change their password.

Default: Not Enforced

Default when Enforced: 5 Days

Allowable Settings: 1 - 365 Days (but also limited by the Minimum and Maximum Password Age settings)



#### Prohibit Recycling of Password for...

When this policy is enforced, all previous passwords are stored in the database and it prevents users from re-using old passwords for the specified number of days.

Default: Not Enforced

Default when Enforced: 180 Days Allowable Settings: 1 – 365 Days



#### Passwords Require Both Alpha and Numeric Characters...

When this policy is enforced, all passwords must contain both alpha and numeric characters.

Default: Not Enforced

#### **Account Lockout**

The following policies determine how and when users' accounts are locked and unlocked. When a user's account is locked, they are not allowed access into the system until an administrator has freed their account. An account is freed when the InfinityQS Administrator resets the user's password from the Database Manager application.

#### Idle Account: Lock account if idle for ...

Anytime the user does not log in for the specified number of days, their account is permanently locked until a system administrator resets the users password and frees the lock.

Default: Not Enforced

Default when Enforced: 30 Days

Allowable Settings: 1 – 365 Days



#### Bad Login Attempts: Lock Account if Attempts Exceed

InfinityQS keeps track of the number of times a user unsuccessfully enters their password. If the number of unsuccessful attempts exceeds this setting, the user's account is locked for the duration specified by the *If Bad Login Attempt Counter is Exceeded: Lock Account for...* setting (described below) or indefinitely if this policy is not enforced.

Default: Not Enforced

Default when Enforced: 3 Attempts

Allowable Settings: 1 - 99 Attempts



#### Reset Bad Login Attempt Counter after...

Each time a user unsuccessfully attempts to access InfinityQS SPC Suite, the user's *Bad Login Attempt Counter* is incremented. This counter is automatically reset to zero (0) once a successful login is performed. It can also be reset to zero (0) based on a period of idle time. This setting determines when that count can be reset back to 0.

For example, the user attempts to login and enters the wrong password. The counter is incremented and the last attempt time is logged. If the user waits until the time specified by this policy setting elapses, the retry counter is reset prior to making the next login attempt.

Default: 30 Minutes

Allowable Settings: 1 – 60 Minutes

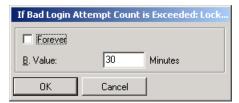


#### If Bad Login Attempt Counter is Exceeded: Lock Account for ...

If the user exceeds the Bad Login Attempts count, their user account is locked until the duration specified elapses or an administrator manually unlocks the user's account.

Default: 30 Minutes

Allowable Settings: Forever, or 1 - 60 Minutes



#### **Access Log**

User Access logs exist for both successful and unsuccessful login attempts. These settings provide login access traceability for companies wishing to track this information.

#### Create Log of User Access

Logs successful logins to the database each time a user logs in. Login records are stored in the Access Log (ACC\_LOG) database table.

Default: No

Allowable Settings: Yes or No

#### Create Log of User Access Violations

Logs unsuccessful logins to the database each time a user exceeds the specified number of Bad Login Attempts (above). Unsuccessful login records are stored in the Access Failure Log (ACC\_FAIL) database table.

Default: No

Allowable Settings: Yes or No

#### **Account Activity**

These security policy settings are applicable for all active users (those currently logged into the system).

#### Signout if Inactive for ...

While a user is logged in to an InfinityQS application, the system watches for key press and mouse click activity. If no activity occurs for the amount of time specified by this setting, the user is required to log back in before they may continue.

Default: Not Enforced

Default when Enforced: 30 Minutes

Allowable Settings: 1 – 60 Minutes



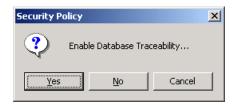
#### **Database Traceability**

The optional traceability functionality within the 2002 release is comprehensive in its ability to track all changes to the database to the person and time in which they occurred. Additionally, all changes are mapped to the original record such that a complete history of the record and its changes are available.

#### Enable Database Traceability...

The first time traceability is enabled, InfinityQS must be closed and then reopened to create the additional tables.

Default: No



#### Traceability in InfinityQS

When the optional traceability functionality within the 2002 release is enabled, a traceability table is created for each active table in the database. These tables are used to maintain a complete history of changes to the database.

#### New Traceability Fields

Every record or record group within the InfinityQS database contains the following traceability fields:

- 1. Create Date: The date and time when the record was created.
- 2. Edit Date: The date and time when the record was last edited.
- 3. User: The user who was logged into the InfinityQS System and is responsible for the creation and/or edit of the record.
- 4. Revision ID: A mapping to revision information associated to edits of the record.
- 5. Delete Status: A status flag to indicate the current status of the record.

#### **Record Modifications**

A complete copy of the original record with all of the traceability fields is saved into a traceability table before the record is allowed to be modified or edited. This ensures that a complete history of all changes to the database is maintained. A complete history of any record, its prior values, who and when the changes were made is available from database manager by enabling the "Show Traceability Tables" in the Report Setup dialog for the specific table. When enabled for display, the traceability records are displayed as yellow rows.

	Process Group	Name	Factor	User	Disable	
6	Can Fab Lines	Can Fab Line 1	1.000000			
7	Cripming	Press #23	1.000000			*
3	Cripming	Press #24	1.000000	Hector Lingus	0	
9	Cutting Center	Cut Off Saw A	1.000000		1/3	
0	Cutting Center	Cut Off Saw B	1.000000			
1	Drilling Center	Drill Press 35-80	1.000000			

#### **Record Deletions**

Generally speaking, record deletions should not be allowed except in specific controlled circumstances by high-level users with appropriate security access. InfinityQS 2002 release supports this functionality by restricting users to specific activities based on their security profiles.

When traceability is enabled, InfinityQS 2002 does not actually delete records from the database. Instead, when a record is "deleted," its *Delete Status* is actually modified to indicate the record is unavailable or deleted. Because this operation is viewed as a record modification, a copy of the original record is stored in the traceability table prior to allowing the Delete Status to be updated. The modified record is then moved to the traceability table providing user and time information of when the delete occurred.

#### Data Entry Sign In / Sign Out

The following policies are designed to implicitly define the logged in user for each data value. They are designed to be used in situations where the customer requires identification with absolute certainty.

#### Sign in Before Beginning Data Entry

Default: Not Enforced

When enabled, the user must sign in before beginning each data entry sequence.

#### Sign in Before Saving Entered Data

Default: Not Enforced

When enabled, the user, after entering the data to the data entry window, must sign in before data can be saved to the database.

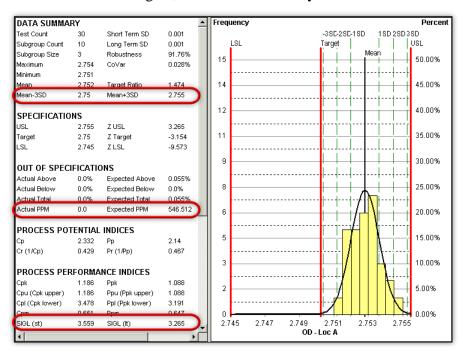
#### Sign out After Completing Data Entry

Default: Not Enforced

When enabled, the user is automatically signed out of the system after the subgroup is saved.

## **Enhanced Six Sigma Support**

InfinityQS has long supported the Six Sigma initiative. As our commitment to Six Sigma, we have added many new features.



### Both long-term and short-term Sigma Level calculations

For variables data, the sigma level calculation is now included in Capability Analysis, Capability Report and Box Plot reports. Sigma level is calculated for both short-term and long-term. Sigma Level (st) is based on Cpk and Sigma Level (lt) is based on Ppk. On the Box Plot, the Sigma Level is based on Ppk.

For attribute data, the Sigma Level is included in the Pareto report and is based on fallout rates.

#### **Actual PPM and Expected PPM**

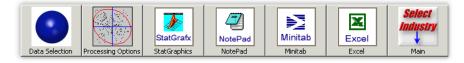
The Capability Analysis and Capability Report now include an Actual PPM (Parts Per Million fallout) and Expected PPM.

# Mean + 3 standard deviations and mean – 3 standard deviations

The Capability Analysis and Capability Report now include the Mean  $\pm$  3 standard deviations. The calculation uses long-term standard deviation.

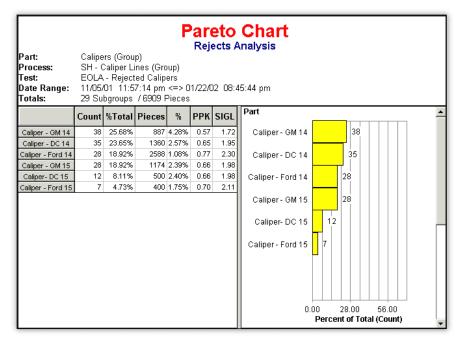
# Integration with Minitab, Statistica, JMP, StatGraphics and Excel

InfinityQS' new Universal Link feature allows the user to send data to any data analysis software product. Configurations for Minitab, Statistica, JMP, Excel, Word and Notepad are pre-configured. Other applications can easily be added by the user. With a single button click, the third party application is loaded and data from InfinityQS is copied into the application's spreadsheet or input file. This new feature greatly simplifies the task of sending data to one's favorite post-analysis software product.



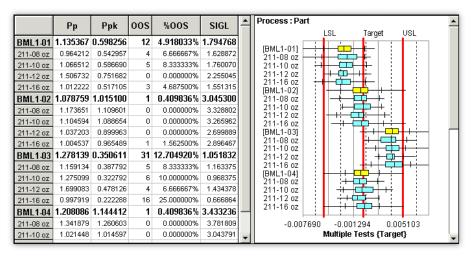
#### **Equivalent Ppk based on Defect or Defective Rates**

The Pareto chart now displays an Equivalent Ppk based on defect or defective rates. For example, a process with a 1,350 PPM fallout corresponds to a Ppk of 1.00.



#### % Out of specification reports

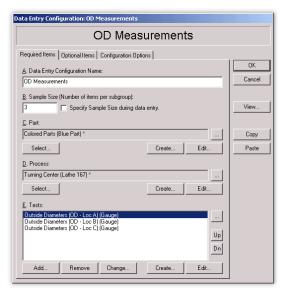
The Capability Analysis has always supported % Out of Specification calculations. These calculations have now been added to the Capability Report and Box Plot.



## **New Data Entry Options**

#### **Improved Data Entry Configuration Window**

The data entry configuration has been transformed from a multi-step wizard into a single dialog box where all data entry functions are set and configured. Additionally, several new data entry options have been added and existing options are better managed. The various options are now organized into three folders *Required Items*, *Optional Items* and *Configuration Options*. We have also implemented a feature that has been requested by many of our customers, the ability to copy and paste Data Entry Configurations, even across projects!

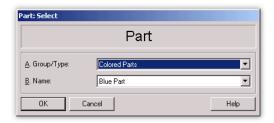


#### **Part Configuration**

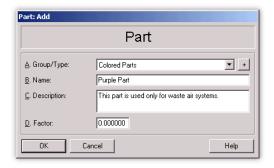
The *Required Items* folder is where the user configures the Parts, Processes and Tests. The Part and Process items are configured using the Select... Create... and buttons.



Clicking the Select. button displays the Part: Select window that allows the selection of a part group and a part item.

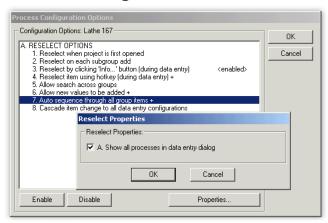


The Create... button displays the *Part: Add* window that allows the creation of new parts in the database. As with all database items in this version, a 63 character description can now be added to each item record. The Edit button displays the *Part: Edit* window.

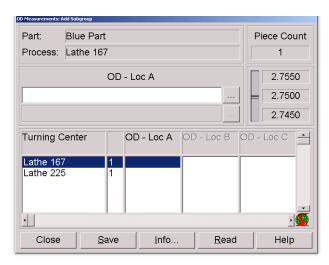


All part selection options are accessed by clicking on the button. The options are enabled by double-clicking on the desired option, by using the arrows to navigate and the space bar to enable, or by utilizing the *Enable/Disable* buttons in the lower left of the options window. Enabling the new option *Cascade item change to all data entry configurations* will cause all data entry configurations within the project to update with the currently selected part item. This feature allows a user to quickly update the part in <u>all</u> data entry configurations with a single (>>depart) toolbar button click or whenever the part is changed during a data entry sequence.

#### **Process Configuration**



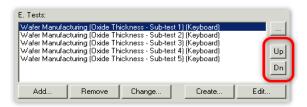
Process selection is very similar to part selection with the exception of the options. Like previous versions, the data entry could sequence through all process group items. This feature has been improved by allowing the option of auto-sequencing or to simply display all the process group items in the data entry window.



When enabled, all processes belonging to the active process group are displayed in the data entry window. This enhancement provides a tremendous level of new flexibility.

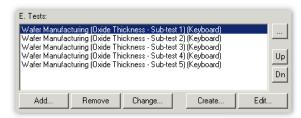
# Tests can more easily be inserted, moved and removed from an existing Data Entry Configuration

Test characteristics can now be moved up and down and even inserted or removed from within an existing data entry sequence. However, caution must be taken when moving or removing tests from configurations containing calculations.



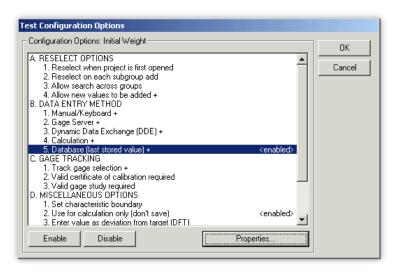
#### Better management of subtest data entry

To set up subtest, from within the Data Entry Configuration window, simply *Add* the same test item to the *Tests* list multiple times. In the example below, Oxide Thickness was added five times. The software automatically treats these multiple test entries as sub-test (within-piece measurements). Even though the data is processed as sub-tests, the data entry window allows all the flexibility given to unique test characteristics. That is, all the data entry and gauging options can be individually applied to each sub-test characteristic. Even individual sub-test values can be included in Equation Editor formulas.

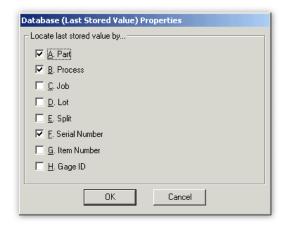


#### Use last stored value

The Database (last stored value) will copy previously entered database values into a current data entry window.



The default value will be the last test value from the currently selected test. However, the search can be further refined by finding the last stored value by combinations of user-selectable criteria (see following example).

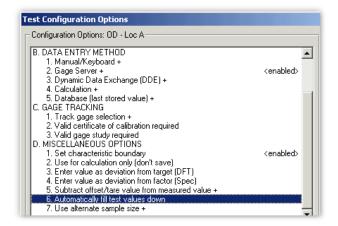


With Part, Process and Serial Number enabled, the value found will be the last stored value for the test characteristic that also matches the data entry configuration's current part, process and serial number.

#### Auto fill test values

When enabled, the value entered as Item 1 for the test characteristic will automatically fill down the remaining items in the subgroup for the given

test. This option is extremely helpful where a test (such as a tare vale) is measured once but used for every item in the subgroup.



#### Cascade item change to all data entry configurations

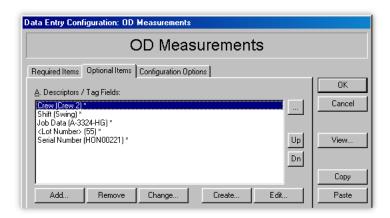
This feature is supported for part, process and descriptors. When enabled, a single change will automatically update all data entry configurations within the active project. This eliminates the need for redundant updates across each data entry configuration. This operates in the same fashion as the little known (-1) parameter in the toolbar.



#### **Alphanumeric Descriptors**

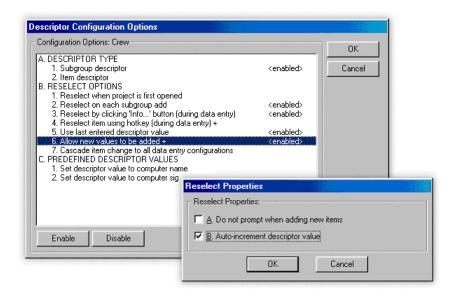
Descriptors are configured within the Optional Items folder. There are five types of descriptors – User Defined, Shift, Job, Lot and Serial Number. All but User Defined descriptors are stored with the subgroup record.

With the exception of Lot, these subgroup-level fields are now alphanumeric. (The user defined descriptors have always accepted alphanumeric characters.)



#### **Auto-Increment Descriptors**

Any descriptor that contains numeric characters can be set to auto-increment. During data add, InfinityQS will increment, by one, the first set of numeric values. For example, DA11215FY will increment to DA11216FY when the option is enabled. To enable, highlight the desired descriptor from the list and click the \_\_\_\_\_ button. Select *Allow new values to be added* and then click the \_\_\_\_\_ button. Select Auto-increment descriptor value from the Reselect Properties dialog box. This auto-increment functionality works equally well with both *subgroup* and *item* descriptors.

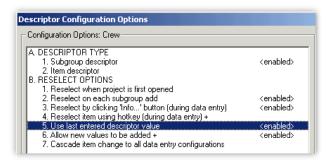


#### **Predefined Descriptor Values**

Either the computer station name or computer signin name can be flagged to be stored with each subgroup from that workstation.

#### Use last entered descriptor value

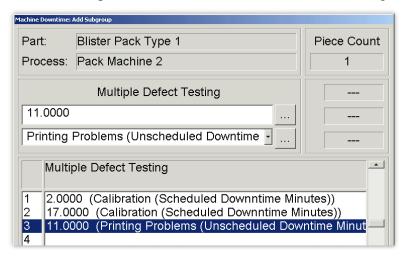
This feature will automatically select the last entered descriptor value into the current data entry.



#### **Group All Defect Codes**

Common applications for this feature are cases where defect codes are organized into multiple defect groups such as Critical, Major and Minor. When enabled, defect codes from all test characteristics are combined into

a single defect code list. This combination simplifies data entry but still maintains unique counts associated with each defect code group.



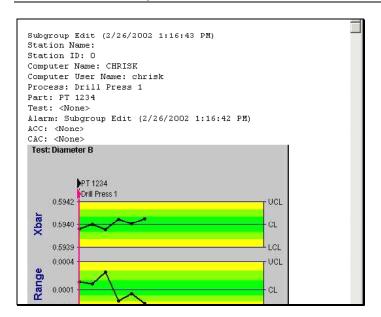
# Increased subgroup size of attribute tests from 30,000 to 10,000,000

For attribute tests, the number of values that can be stored in a single subgroup has been increased from 30,000 to 10,000,000. Variable tests are limited to 1,000 measurements.

## **Improved Event Management**

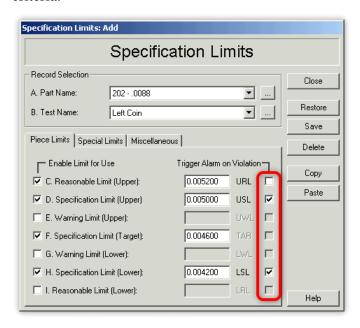
#### Control Chart as .jpg attachment to Email

Email messages now contain the chart graphic that generated the alarm. These graphics are written as .jpg attachments.



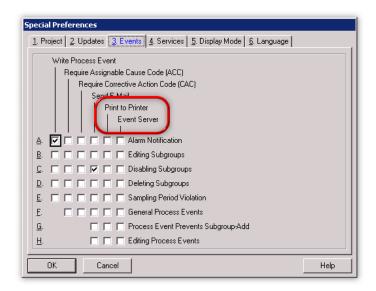
#### **User-Defined Specification Violation Triggers**

Alarms generated by out-of-specification violations are now separate from alarms generated by statistical rule violations. The specification limit record now allows alarms to be uniquely generated based on user-selected criteria.



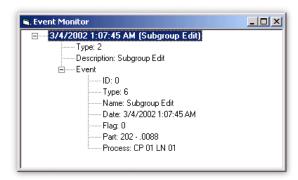
#### **Automatic Event Printing**

When Print to Printer is enabled from within the *Preference>Special>Event* folder, a hard copy Process Event record is automatically printed. The record includes the event type, date, part, process, test, user name, station name, station ID, and any associated action codes, cause codes and comments.



#### **Event Server**

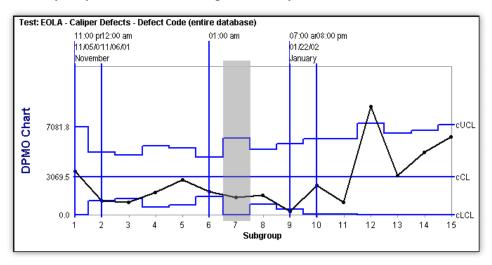
When Event Server is enabled from within the *Preference>Special>Event* folder, the event details will automatically be posted to the Event Server application. The Event Server is a dispatching system used to post events. Other applications subscribing to the Event Server can receive these events and deal with them accordingly. External applications (i.e. traceability systems or closed-loop machine feedback systems) can subscribe to the Event Server. The graphic below is an example of the information that is available.



#### **Chart Enhancements**

#### **Additional Control Chart Markers**

Changes in Job, Lot, Shift and user-defined Time markers have been added to control charts. Time markers can be divided into hours, date, weekday, day of month, month, quarter and year.



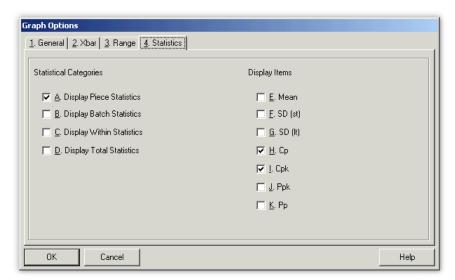
#### **Print and Copy Command from Subgroup Pop-up Window**

Hard copies of individual subgroup information can be copied and printed from within the subgroup pop-up window.



#### **Control Chart Summary Statistics**

Statistics to be displayed are now user-selectable graph options. Pp, Ppk and SD(lt) values have been added to the available variables control chart statistics list.



#### **Color Coded Capability Reports and View Data Charts**

Capability Reports are color-coded based on process performance compared to the Target Cp and Cpk. Red rows indicate the Cp falls below the Target Cp. Yellow rows indicate the Cpk falls below the Target Cpk. The target Cp/Cpk values are specified in the miscellaneous section of the specification record.

CPK Report  Colors Represent Actual vs Desired Outcome  Chart: Capability Report Interpretation: Red = Violated Tar Cp Yellow = Violated Tar Cpk Green = No Cp or Cpk Violations									
Part	Process	Test	Ср	Cpk	Pр	Ppk	Actual PPM	Expected PPM	i
Multiple	Lathe 167	Multiple	1.77	1.76	1.78	1.77	0.00	0.09	
Yellow Part	Lathe 167	OD - Loc A	4.07	3.19	3.84	3.01	0.00	0.00	
Yellow Part	Lathe 167	OD - Loc C	6.05	3.97	0.91	0.60	0.00	36882.41	
Yellow Part	Lathe 225	OD - Loc B	3.17	1.88	3.19	1.90	0.00	0.01	
Yellow Part	Lathe 225	OD - Loc A	10.08	8.02	9.29	7.39	0.00	0.00	
Yellow Part	Lathe 225	OD - Loc C	1.80	1.16	1.83	1.18	0.00	197.48	
			4.39	3.26	3.21	2.46	0.00	0.00	
Blue Part	Lathe 167	OD - Loc B	0.91	0.87	0.90	0.87	0.00	6954.07	
Blue Part	Lathe 167	OD - Loc A	2.33	1.19	2.14	1.09	0.00	546.51	
Nive Part   Lethe 187   Oh   Loc C   0.33   0.33   0.35   0.34   300000 00   320848.57									

On a View Data chart, a red cell is out of specification, and a yellow cell is in specification, but outside of the specified warning limits.

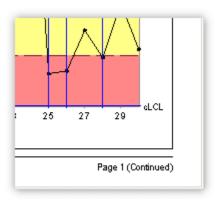
Lot	Date	Time	Size	Test	OD - Loc B	OD - Loc A	OD - Loc C	_
32	07/13/99	03:54:17 pm	3	2	1.4978	2.7514	[1.5093]	
32	07/13/99	03:54:17 pm	3	3	1.5007	2.7516	1.4999	
49	07/13/99	03:37:17 pm	3	1	1.499	2.7531	1.4975	
49	07/13/99	03:37:17 pm	3	2	1.4979	2.7521	1.4984	
49	07/13/99	03:37:17 pm	3	3	1.5005	2.7541	1.4978	
49	07/13/99	03:20:17 pm	3	1	1.4957	2.7524	[1.5071]	
49	07/13/99	03:20:17 pm	3	2	1.5001	2.7537	1.489	
49	07/13/99	03:20:17 pm	3	3	1.5004	2.7525	[1.5051]	
49	07/13/99	03:03:17 pm	3	1	1.5	2.753	1.4976	
49	07/13/99	03:03:17 pm	3	2	1.5024	2.7527	1.4902	
49	07/13/99	03:03:17 pm	3	3	1.5006	2.7524	1.5029	-
4								

# Allow selection of up to 100 items from a group or during Advanced Data Selection

The number of items manually selected from a group or using Advanced Data Selection has been increased to 100.

#### **Printed Pages Show Continuation**

Printouts now contain a footer item to specify if there are additional pages.



#### **Separator Lines on View Data and Process Event Reports**

Separator lines have been added to the report printout of both the Process Event report and the View Data Set report. These lines provide a visual break between events and subgroups in their respective reports.

		ocess Action
Part: Blue Part, ` Process: Entire Data Test: Entire Data	base	
02/19/02 11:45:20 pm 02/19/02 11:45:16 pm	Alarm Violation: Process: Part: Test:	(Xbar) >UCL Lathe 225 Blue Part OD -Loc A
02/14/02 09:53:51 am 02/14/02 09:53:46 am	Alarm Violation: Process: Part: Test:	(Xbar) <lcl Lathe 167 Blue Part OD -Loc A</lcl 
02/13/02 03:47:27 pm 11/02/00 01:04:48 pm	Alarm Violation: Process: Part: Test:	(Moving A) <lcl Lathe 167 YellowPart OD -Loc C</lcl 
02/13/02 03:45:18 pm	Alarm Violation:	(Moving A) <lcl< td=""></lcl<>

## **Project Enhancements**

#### **Graphics in Toolbar Buttons**

Add uniqueness and shop floor acceptability. Any bitmap graphic can be mapped to a toolbar button. Several new images are already included.



#### **Added Print All Toolbar Button**

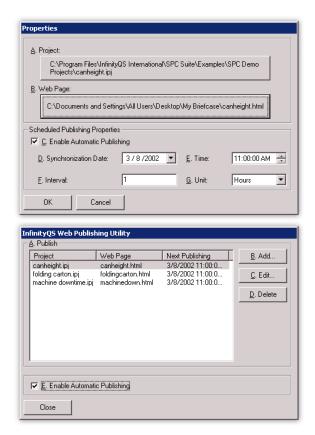
The toolbar command, >>printall has been added to the list of available toolbar commands in the InfinityQS SPC program.

#### **Added Send Toolbar Button**

With a single button click, a third party application is loaded and data from InfinityQS is copied into the application's spreadsheet or input file. This new feature greatly simplifies the task of sending data one's favorite post-analysis software product.

#### **Scheduled Web Publishing of SPC Projects**

The toolbar command >>publish will launch the Web Publishing Utility. This utility is used to specify projects to be published and the web page destination. Publish intervals can be specified. Multiple projects can be added to the list.



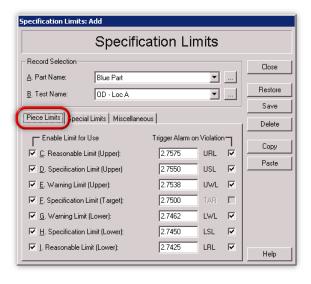
## **JPEG Graphics**

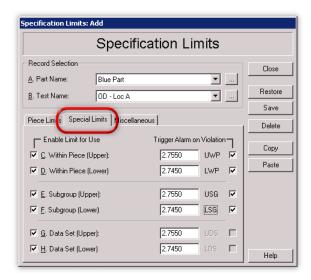
The chart sent to web pages are now JPEG graphics instead of bitmaps.

## **Enhanced Specification Limit Record**

The *Piece Limits* have been enhanced to include Reasonable Limits (outside the specification) and Warning Limits (inside the specification). This replaces the old Guard Band limits. Alarms can also selectively be triggered if these limits are violated.

Special Limits have been added for Within-Piece values, Subgroup values (for when a specification is used for the average of the subgroup), and for Data Sets. A data set is defined by the chart's data selection. Data set limits are used when a specification is defined for the average of a completed *lot*, *job* or *run*.





<<< end >>>